

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The effect of progressive muscle relaxation technique on fatigue, pain and quality of life patients undergoing dialysis

#### Protocol summary

##### Study aim

Determining and comparing the mean total score of fatigue, pain and quality of life in dialysis patients before and three months after the implementation of progressive muscle relaxation technique in the intervention and control groups

##### Design

The clinical trial has a control group and parallel design and it is performed on 60 patients. Randomization will be done by card.

##### Settings and conduct

The above project is performed in the dialysis ward of Ali Ibn Abitaleb and Khatam Al-Anbia hospitals in Zahedan and the technique of progressive muscle relaxation is given individually to the intervention group at the patient's home by the researcher

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People over 18 years old referred to the dialysis ward of the relevant hospitals; suffering from chronic kidney failure; living in Zahedan; having a minimum level of education; willing to participate in the study. Non-inclusion criterion: Need to be hospitalized

##### Intervention groups

In the intervention group, progressive muscle relaxation technique individually face to face in 2 to 3 sessions for one hour, on the day after dialysis, the time of which is determined in coordination with the patient and family, in the presence of a first-degree member of the patient (child, Spouse), is taught at the patient's home by the researcher. (If the patient is not able to perform the technique independently during the designated sessions, the training will continue until the learning is complete and the technique is performed independently). These people should do relaxation exercises twice a day (morning and evening) for 12 weeks according to the schedule set at home. In the control group, nothing will be done except routine care.

##### Main outcome variables

General quality of life, quality of public life, quality of

private life, fatigue, pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201021049107N1**

Registration date: **2022-02-14, 1400/11/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-14, 1400/11/25**

Update count: **0**

##### Registration date

2022-02-14, 1400/11/25

##### Registrant information

##### Name

Mojtaba Kazaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

kazaeim2@moums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-10, 1399/12/20

##### Expected recruitment end date

2022-03-11, 1400/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
The effect of progressive muscle relaxation technique on fatigue, pain and quality of life patients undergoing dialysis

**Public title**  
The effect of progressive muscle relaxation technique on fatigue, pain and quality of life of dialysis patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age over 18 years Performing dialysis 2 to 3 times a week Ability to access and control the patient during the study Resident of Zahedan Having a cell phone by the participant or a family member or having a landline telephone at home Have a minimum degree of literacy At least 6 months have passed since the first dialysis  
**Exclusion criteria:**  
Need to be hospitalized Functional disability (musculoskeletal) Known mental illness

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling will be done by available method. Then the selected patients are randomly divided into control and intervention groups. In this way, some envelopes containing the names of the groups are prepared and randomly arranged for the total number of participants. By referring each patient one of the envelopes will be assigned to them subsequently.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences  
**Street address**  
Campus of Medical School; Dr. Hesabi square  
**City**  
Zahedan  
**Province**  
Sistan-va-Balouchestan  
**Postal code**  
9816743463  
**Approval date**  
2021-03-07, 1399/12/17  
**Ethics committee reference number**  
IR.ZAUMS.REC.1399.539

## Health conditions studied

### 1

#### Description of health condition studied

Dialysis patients

#### ICD-10 code

Y84.1

#### ICD-10 code description

Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

## Primary outcomes

### 1

#### Description

Total fatigue score based on the fatigue questionnaire

#### Timepoint

Before the intervention and three months after the end of the intervention

#### Method of measurement

The Fatigue Questionnaire is a short questionnaire to measure the level of fatigue, it consists of 9 sentences that each sentence is scored according to the severity of the symptoms. The range of scores for each question is between 7-1. Giving the lowest score, 1 indicates strong opposition to the sentence and 7 indicates strong agreement with the sentence. In order to obtain the total score of the questionnaire, the total score of each question is calculated. A higher score indicates the greater the severity of the respondent's fatigue, and vice versa. This score ranges from 9 to 63. In general, the patient with a total score below 36 indicates no fatigue and if the total score is 36 or above 36, indicates fatigue.

### 2

#### Description

The total pain score based on the pain questionnaire

#### Timepoint

Before the intervention and three months after the end of the intervention

#### Method of measurement

Visual Analogue Scale, or VAS, is a scale used to measure pain intensity. It is the most widely used pain

measuring tool in the world. The most important feature of this instrument is its ease of use. The number zero on the left indicates absolute painlessness and the number 10 on the right indicates unbearable pain. A score of 1-3 indicates mild pain, 4-7 indicates moderate pain, and 8-10 indicates severe pain.

### **3**

#### **Description**

The total quality of life score that is measured by the quality of life questionnaire

#### **Timepoint**

Before the intervention and three months after the end of the intervention

#### **Method of measurement**

The standard quality of life questionnaire for kidney patients is a questionnaire of 79 questions and is divided into two subscales, specific and general. General dimension includes 8 areas of general health (6 questions) with a score of 5-1, physical function (10 questions) and a score of 3-1, physical pain (2 questions) with a score of 1-1, playing an emotional role (3 questions) With a score of 2-1, social performance (2 questions) with a score of 1-1, vitality (4 questions) with a score of 6-1, mental health (5 questions) with a score of 6-1 and physical role playing (4 questions) with a score It is 2-1. Specific dimension includes 12 burden areas of kidney disease (4 questions) with a score of 1-5, cognitive function (3 questions) with a score of 1-5, quality of social interactions (3 questions) with a score of 1-5, symptoms (12 questions) with a score of 5-1, Effect of kidney disease (8 questions) with score 5-1, Sexual issues (2 questions) with score 5-1 Sleep (4 questions) with score 5-1, Social support (2 questions) with score 4-1 , Work status (2 questions) with a score of 2-1, Patient satisfaction (1 question) with a score of 1-7, Satisfaction with the care of ward staff (2 questions) with a score of 1-5 and General health rating (1 question) with a score It is 10-0. According to the standard guidelines for quality of life in kidney patients, a score of 0 to 100 is assigned for each dimension. In addition, the total scores from both subscales were classified as poor (0-33), moderate (34-66) and good above 66.

### **4**

#### **Description**

General quality of life score that is measured by the quality of life questionnaire and its score range is from 0-100

#### **Timepoint**

Before the intervention and three months after the end of the intervention

#### **Method of measurement**

The standard quality of life questionnaire for kidney patients is a questionnaire of 79 questions and is in 2 subscales. The general dimension includes 8 areas of general health (6 questions) with a score of 1-1, physical function (10 questions) and a score of 3-1, physical pain (2 questions) with a score of 6-1, playing an emotional role (3 questions) with a score of 2-1, social performance (2 questions) with a score of 5-1, vitality (4 questions)

with a score of 6-1, mental health (5 Question) with a score of 1-6 and playing a physical role (4 questions) with a score of 1-2. According to the standard guidelines for quality of life in kidney patients, a score of 0 to 100 is assigned for each dimension. In addition, the total scores from both subscales were classified as poor (0-33), moderate (34-66) and good above 66.

### **5**

#### **Description**

Specific quality of life score that is measured by the quality of life questionnaire and its score range is from 0-100

#### **Timepoint**

Before the intervention and three months after the end of the intervention

#### **Method of measurement**

The standard quality of life questionnaire for kidney patients is a questionnaire of 79 questions and is in 2 subscales, which includes a specific dimension including 12 areas of kidney disease burden (4 questions) with a score of 1-5, cognitive function (3 questions) with a score of 1-5, quality of social interactions (3 questions) with a score of 5-1, symptoms (12 questions) with a score of 1-1, the effect of kidney disease (8 questions) with a score of 1-1, sexual issues (2 questions) with a score of 1-1, sleep (4 questions) With a score of 5-1, social support (2 questions) with a score of 4-1, working status (2 questions) with a score of 1-2, patient satisfaction (1 question) with a score of 7-1, satisfaction with the care of ward staff (2 questions) ) With a score of 5-1 and the overall health rating (1 question) with a score of 10-0. According to the standard guidelines for quality of life in kidney patients, a score of 0 to 100 is assigned for each dimension. In addition, the total scores from both subscales were classified as poor (0-33), moderate (34-66) and good above 66.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: First, a questionnaire of demographic characteristics, fatigue, pain and quality of life for patients is completed by the researcher. Then, the technique of progressive muscle relaxation individually face to face in 2 to 3 sessions for one hour, on the day after dialysis, the time of which is determined in coordination with the patient and family, in the presence of a first-degree member of the patient (child, spouse) is taught at the patient's home by the researcher (If the patient is not able to perform the technique independently during the designated sessions, the training will continue until the learning is complete and the technique is performed independently). The first session will be technique training; the second session will be performing the technique by the patient in the

presence of the researcher and the repetition of the technique training if necessary. The third session will be training with questions from the patient and answers to his questions during practice relaxation technique at home and performance and performing technique by the patient in the presence of the researcher. The audio file is provided to the intervention group through a compact disc with the researcher's own voice and an educational booklet containing images of the first and second steps of relaxation. The intervention group is asked to do relaxation exercises twice a day (morning and evening) for 12 weeks according to the schedule set at home. Each relaxation step takes about 20 minutes. The family member is also asked to supervise the patient performing the technique at home. Prior to the intervention, the researcher will undergo theoretical and practical training in relaxation techniques in several stages under the full supervision of a clinical psychologist. The technique is performed by first closing the patient's eyes, relaxing them as much as possible, and focusing all their attention on their breathing, taking five deep breaths, and each time filling the lungs with air and empty slowly. After this stage, patients perform muscle contraction and expansion for 14 groups of facial muscles (forehead, eyelids, jaws, and lips), neck muscles, fingers and palms, forearms, arms and shoulders, back and chest, abdomen, buttock, thighs, legs and soles of the feet. Each muscle contracts for 5 seconds and expands for 10 seconds. Also, when the muscles contract, they should not tighten too much, and shouldn't put pressure on themselves rather, normal contraction will be sufficient. Finally, the patient relaxes his whole body, takes 5 deep breaths, opens his eyes slowly, and returns to normal. During this period, to ensure the implementation of the relaxation technique on the prescribed days, a checklist is provided to the patient's family member to record the day, hour and duration of the technique by the patient and if not, the cause. Also, in order to solve possible problems in the implementation of the technique, during the research, the researcher made telephone calls to the patient or family member twice a week to ensure the implementation of the technique and the completion of the checklist. After 12 weeks, the researcher completes the fatigue, pain and quality of life questionnaire for the intervention group.

#### **Category**

Rehabilitation

## **2**

#### **Description**

Control group: First, to start the pre-test, a questionnaire of demographic information, fatigue, pain and quality of life was completed by the researcher. This group does not receive any intervention except for routine care. The post-test is completed within 12 weeks during a telephone call by the researcher whose time and place are based on the wishes and opinions of the patient and his family. At the end of the intervention, the audio file on a CD with the researcher's own voice and an educational booklet with an image containing the first and second steps of relaxation will be provided to

patients in the control group and family.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Ali Ibn Abitaleb Hospital; Zahedan University of Medical Sciences

##### **Full name of responsible person**

Mahnaz Ghaljeh

##### **Street address**

Ali Ibn Abitaleb Hospital; Salamat Boulevard; Khalij-e-Fars Highway; Zahedan

##### **City**

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Sistan-va-Balouchestan

##### **Postal code**

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### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Khatam Al-Anbia Hospital, Zahedan University of Medical Sciences

##### **Full name of responsible person**

Mahnaz Ghaljeh

##### **Street address**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Zahedan University of Medical Sciences

##### **Full name of responsible person**

Noor Mohammad Bakhshani

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 public@zaums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Zahedan University of Medical Sciences  
**Proportion provided by this source**  
 100  
**Public or private sector**  
 Public  
**Domestic or foreign origin**  
 Domestic  
**Category of foreign source of funding**  
 empty  
**Country of origin**  
**Type of organization providing the funding**  
 Academic

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
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**Full name of responsible person**  
 Mahnaz Ghaljeh  
**Position**  
 University faculty member, assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
 Nursery  
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
 Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
 Undecided - It is not yet known if there will be a plan to make this available  
**Statistical Analysis Plan**  
 Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available